

REMARKS/ARGUMENTS

This is in response to the Office Action mailed December 29, 2005.

Claims 2 and 8 have been amended. Support for amendments to claims 2 and 8 can be found throughout the originally filed application, e.g., paragraph 37 and originally filed claim 1, respectively. No new matter is introduced and these are not intended to be narrowing amendments.

Independent claim 1 and its dependent claims 2-7 and independent claim 8 and its dependent claims 9-10 are currently pending and at issue.

Election - 35 U.S.C. §121

The Examiner asserts that claim 6 is generic to a plurality of disclosed patentably distinct species comprising disease and that the Applicant is required to elect a single disclosed species. As the Examiner noted, during a December 20, 2005 telephone conversation, to expedite prosecution of the case, Applicants made a provisional election to prosecute the invention of diabetes mellitus.

The Applicants affirm the election of the species directed to diabetes mellitus. Claims 1-10 are readable on the elected species. Should the examiner find the elected species patentable, it is then respectfully requested that the non-elected species be examined. The Applicants reserve the right to file a divisional application to all subject matter or claims withdrawn, cancelled or restricted out. The Applicants elect these embodiments with traverse.

Claim Rejections - 35 U.S.C. §112, first paragraph

The Examiner has rejected claim 2 under 35 U.S.C. §112, first paragraph, because allegedly the specification, while being enabling for mammals, does not reasonably provide enablement for non-mammalian species.

To expedite prosecution of the application, claim 2 has been amended to recite mammalian pets. The Applicants respectfully request that this rejection be withdrawn.

Claim Rejections - 35 U.S.C. §103

The Examiner has rejected claims 1-7 under U.S.C. § 103(a) as being unpatentable over Metz et al (AJH 1:58-60 1988). The Examiner asserts that Metz teaches a reduction in body fat in rats consuming higher diets of calcium and that it would have been obvious to one of ordinary skill to formulate a high calcium diet for humans to achieve the beneficial effect of a reduction in body fat content in view of the Metz results.

However, the Examiner has not established a *prima facie* case of obviousness as set forth in MPEP §§ 706.02(j) and 2143. Metz does not teach or expressly or impliedly suggest any of the limitations set forth in the present claims. There is no motivation to combine the references with other knowledge and there would not be a reasonable expectation of success.

In addition, the Applicants are submitting a variety of evidence showing the present invention's unexpected results, which has led to a significant shift in the scientific community and the food industry, which has supported and endorsed the methods of the present invention leading to significant recognition and commercial success.

Currently independent claim 1 is directed to a method of regulating weight comprising

administering dairy products in an amount sufficient to induce weight loss, prevent weight gain, and/or increase the metabolic consumption of adipose tissue in a non-human animal.

Applicants contend that the present invention is distinct from Metz, which does not disclose, teach or suggest any of the elements of independent claim 1. In fact, nowhere in Metz is dairy mentioned or used.

Metz is directed to a hypothesis of testing the modification of body fat using the simultaneous administration of calcium with sodium. In the introduction, Metz teaches that some reports indicate supplementation of both dietary calcium and sodium results in a beneficial interaction between these two cations. The experiments were conducted on rats in three groups receiving: (1) high calcium/ high sodium, (2) moderate calcium/ moderate sodium and (3) low calcium/ low sodium. The results show that groups receiving higher amounts of calcium with sodium resulted in body weight reductions.

As set forth in the discussion, Metz teaches that "[t]o date, Ca^{2+} intervention trials in humans with hypertension have not noted significant reduction in body weight with Ca^{2+} supplementation." Metz further teaches that: "[d]ietary sodium was simultaneously modified in this study, as earlier investigations had demonstrated that calcium effects on blood pressure were, in part, sodium-dependent. Thus, concurrent manipulations of Ca^{2+} and Na^+ were utilized in this study." Metz concludes that "current results confirm that body fat and weight can be favorably modified by increasing the dietary content of both calcium and sodium."

Metz uses both "calcium and sodium" to show body weight changes. Metz does not mention or use dairy and does not show or suggest that specifically dairy is responsible for the weight benefits as set forth in claim 1. The hypothesis of Metz regarding the synergistic effects

of calcium with sodium on body fat and weight has nothing to do with dairy. Unlike Metz, the present invention specifically shows that dairy alone induces weight loss, prevents weight gain, and/or increases the metabolic consumption of adipose tissue in a non-human animal.

Therefore, Metz does not teach or suggest the use of dairy products in an amount sufficient to induce weight loss, prevent weight gain, and/or increase the metabolic consumption of adipose tissue in a non-human animal.

Moreover, prior to the invention recited here, there was no recognition that administering dairy products induces weight loss, prevents weight gain, and/or increases the metabolic consumption of adipose tissue in a non-human animal. The importance of administering dairy products to induce weight loss, prevent weight gain, and/or increase the metabolic consumption of adipose tissue in a non-human animal was previously unrecognized and was unexpected prior to Dr. Zemel's team's pioneering work.

Due to these unexpected results, there has been a significant shift in the scientific community and the food industry, which has supported and endorsed the methods of the present invention. The inventive methods have achieved considerable public recognition and commercial success in relation to human nutrition, as indicated by the attached documentation.

Page one of the attached material lists various clinical trials conducted by Dr. Zemel further showing the beneficial effects of consuming high calcium and dairy in accelerating the effects of weight loss in humans. This is consistent with the animal data in the specification. Page two shows how the food industry has adopted the novel methods of the present invention. For example, the label "3-A-Day Milk Cheese Yogurt, Burn more fat, lose weight" communicates the message that increasing dairy consumption to at least three servings a day supports weight loss. As set forth on

page two, over 50 top U.S. retail chains have licensed the inventive methods and are promoting the inventive methods by placing labels with the weight loss message on over 2.5 billion dairy packages to date. Pages three, four and five evidence various examples of leading industry packages and consumer advertisements. Page six provides testimonials about the inventive methods from notable health professional associations. The American Academy of Family Physicians refers to "dairy nutrition and its contribution to weight management." The National Medical Association recognizes that "[s]ome of the information that was presented today shows a clear beneficial relationship between the daily intake of three to four servings of dairy products and the reduction of obesity." The American Dietetic Association praises Dr. Zemel's work in that "[i]t has been exciting to see how emerging research on the role of calcium and dairy products adds to the body of knowledge about preventing and treating obesity [and t]his information provides additional tools for dietetics professionals to use in their day-to-day practice."

Therefore, Metz, either alone or in combination with other knowledge, does not disclose, teach or suggest the claimed invention as set forth in claim 1 or its dependent claims 2-7, which include additional limitations distinguishing them from the cited references, e.g., in claim 2, wherein the animal is a pet; in claim 3, wherein the animal is a dog or cat; in claim 4, wherein the animal is a mouse; in claim 5, wherein the animal is a farm animal; in claim 6, wherein the method reduces the risk of diabetes mellitus; and in claim 7, wherein the dairy products are administered in an amount sufficient to treat, reduce or attenuate obesity.

The Examiner further contends that as to the reduced risk of diabetes (as set forth in claim 6), it is allegedly well known that obesity increases the risk of diabetes, and therefore, a method of reducing weight will reduce that risk. The Examiner asserts that one of ordinary skill would

further recognize that mammals in general are subject to this risk.

However, one would not be motivated to combine the teaching of Metz with this knowledge because Metz does not teach, disclose or suggest a method of administering dairy to induce weight loss, prevent weight gain and/or increase the metabolic consumption of adipose tissue in a non-human animal, nor wherein the method also reduces the risk of diabetes mellitus. Instead, Metz simply teaches the use of calcium with sodium.

Also, as discussed above the use of dairy to induce weight loss, prevent weight gain and/or increase the metabolic consumption of adipose tissue in a non-human animal was not previously recognized and would have been unexpected at the time the application was filed. Therefore, claim 6 is unobvious over Metz and other cited prior art.

As discussed above, claims 1-7 are patentable over Metz because it does not disclose, teach or suggest the present invention. This rejection is traversed. The Applicants respectfully request that this rejection be withdrawn.

Claim Rejections - 35 U.S.C. §102

The Examiner has rejected claims 8-10 under U.S.C. § 102(2) as being unpatentable over Schroeder et al (U.S. Patent No. 4,027,043). The Examiner asserts that Schroeder teaches a solid animal feed supplement containing calcium, which is poured into packages. The Examiner contends that ruminants are disclosed and as to the claimed pet food, such is allegedly merely an intended use. The Examiner concludes that as to the claimed description, such a limitation is not considered patentable during prosecution of composition claims before the USPTO.

The Applicants disagree with the Examiner's premise that the claimed description is not a patentable limitation. In *In re Ngai*, 217 USPQ 401, 404 (Fed. Cir. 2004) and *In re Gulack*, 703

F.2d 1381 (Fed. Cir. 1983), the Court has held that printed matter can be a patentable limitation if the printed matter is functionally related to the claimed product and the content of the printed matter distinguishes the claimed product from the prior art. (See MPEP section 2112.01, III).

In fact, *Gulack* states that "[d]ifferences between an invention and the prior art cited against it cannot be ignored merely because those differences reside in the content of the printed matter." [p. 1358]. It further states that "[u]nder 103, the board cannot dissect a claim, excise the printed matter from it, and declare the remaining portion of the mutilated claim to be unpatentable..." [Id.] The "claim must be read as a whole", [Id.] to determine if there is a new and unobvious functional relationship between the printed matter and the product.

The present claims include a printed matter element that is functionally related to the product. Current independent claim 8 is directed to an animal food package comprising a product, a calcium-fortified or dairy-containing animal food, and printed matter in the form of a description of the benefits of consuming calcium in inducing weight loss, preventing weight gain, and/or increasing the metabolic consumption of adipose tissue, which is functionally related to the product.

The claims include a product, either a calcium-fortified or dairy-containing animal food, and printed matter, e.g., the description, that is functionally related to the product, e.g., the benefits of consuming calcium in inducing weight loss, preventing weight gain, and/or increasing the metabolic consumption of adipose tissue, which is functionally related to the product. The present claims include printed matter that is functionally related to the claimed product and the content of this printed matter distinguishes the claimed product from the Schroeder.

Schroeder discloses an animal feed supplement in solid, block form which is sufficiently

palatable to permit its free choice feeding and which contains the proper proportions of molasses and/or fat to supply the energy requirements for maintenance and weight gain of the animals (abstract). At most Schroeder discloses that the feed supplement includes solidifying ingredients comprising a phosphate and an oxide or salt of a metal such as calcium in quantities sufficient to solidify the supplement into solid, block form (abstract).

However, nowhere in Schroeder is it disclosed, taught or expressly or impliedly suggested, as set forth in present claim 8, a description of the benefits of consuming calcium in inducing weight loss, preventing weight gain, and/or increasing the metabolic consumption of adipose tissue in a non-human animal. Therefore, Schroeder does not anticipate or render obvious the present claims.

In fact, one would not be motivated to modify or combine the teaching of Schroeder to achieve the results of inducing weight loss, preventing weight gain, and/or increasing the metabolic consumption of adipose tissue in a non-human animal, because Schroeder teaches the opposite, "maintenance and weight gain of the animals" and therefore would lead away from the teachings of the present claims. Moreover, at the time the application was filed the use of dairy or calcium-fortified products in inducing weight loss, preventing weight gain, and/or increasing the metabolic consumption of adipose tissue in a non-human animal, was not previously recognized and would have been unexpected, as discussed above.

Therefore, Schroeder, either alone or in combination with other knowledge, does not disclose, teach or suggest the claimed invention as set forth in claim 8 or its dependent claims 9 and 10, which include additional limitations distinguishing them from the cited references, e.g., in claim 9, wherein the animal food is pet food; and claim 10, wherein the animal food is farm

animal feed.

As discussed above, claims 8-10 are patentable over Schroeder because it does not disclose, teach or suggest the present invention. This rejection is traversed. The Applicants respectfully request that this rejection be withdrawn.

**Double Patenting
Non-statutory Rejection**

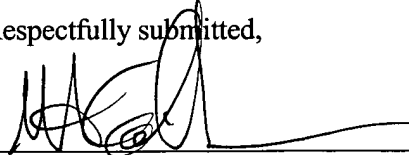
Claims 1-7 were rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-66 of prior U.S. Patent No. 6,384,087. To expedite prosecution of the application, Applicants submit herewith a terminal disclaimer in compliance with 37 CFR 1.321(c), to overcome the rejection.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. Accordingly, Applicants request that the Examiner issue a Notice of Allowance indicating the allowability of claims 1-10 and that the application be passed to issue. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is hereby invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Michael A. Gollin', written over a horizontal line.

Date: March 29, 2006

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